

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Jonathan L. Nicozisis

Serial No. : 10/666,163

Filed : September 19, 2003

Art Unit : 3732

Examiner : Ralph A. Lewis

Attorney Docket: NIC043 - 230540PT1

Title: APPARATUS AND METHOD FOR REMOVING A REMOVABLE TOOTH
POSITIONING APPLIANCE FROM THE TEETH OF A PATIENT



AFFIDAVIT OF DR. WM. RANDOL WOMACK, D.D.S. UNDER 37 C.F.R. § 1.132

1. I, Wm. Randol Womack, am an individual residing at 2519 E. Palo Verde Drive, Phoenix, Arizona 85016 and am a citizen of the United States of America
2. I have received the following dental education and/or have obtained the following dental degrees: (1) University of Missouri, School of Dentistry, Doctorate of Dental Surgery; (2) Eastman Dental Center, performed Pedo Internship in 1964; and (3) Eastman Dental Center, received Orthodontic Degree in 1966.
3. I practiced orthodontics from 1966 to 1997. I retired from 1997 to 1999. In 1999, I was Invisalign Certified to fit, apply, and prescribe removable tooth positioning appliances, such as the one disclosed in FIG. 1 of the present U.S. Patent Application (Serial No. 10/666,163), which are typically sold under the brand name Invisalign®.
4. My additional professional and/or academic credentials and accomplishments are set forth in my Curriculum Vitae, a copy of which is annexed hereto.
5. As an Invisalign certified orthodontist, I am currently practicing orthodontics part-time at both 15050 North 69th St., Scottsdale, Arizona 85253 and at 5310 and at 5310 West Thunderbird Drive, Glendale, Arizona 85306. Since 1999, my practice of orthodontics has included the fitting, application, and prescription of removable tooth positioning appliances, such as the one disclosed in FIG. 1 of the present U.S. Patent Application (Serial No. 10/666,163), which are typically sold under the brand name Invisalign®.
6. Since 1999, there has been a need for an orthodontic tool and method that is suitable for removing these removable tooth positioning appliances from the teeth of patients. I, personally, have been aware of this need since 1999 and the need has been persistent. To the best of my knowledge, despite the existence and recognition of this need in the art, no orthodontic tool or method was developed prior to the present invention that satisfied this need.

Docket No. NIC043-230540

PATENT

Serial No. 10/666,163

§ 1.132 Affidavit of Wm. Randol Womack, DDS

7. I have reviewed and am familiar with the orthodontic tool, system, and method disclosed and claimed in the present United States Patent Application 10/666,163.

8. I have also reviewed and am familiar with the orthodontic tool disclosed in United States Patent 2,602,998 ("Sprague"). The Sprague tool is not suitable for removing the removable tooth positioning appliances. The Sprague tool is designed for use with the prosthetic dental devices, such as dentures, and for the removal of tartar. The sharp edge of the Sprague tool is designed to engage a hook/clasp of a prosthetic. To the contrary, in order to remove a removable tooth positioning appliance, such as the Invisalign®, the sharp edge of the Sprague tool would have to be wedged in between the removable tooth positioning appliance and the gums/teeth of the patient. This would present the danger of damaging the gums/teeth of the patient. One skilled in the art would not use the Sprague tool to remove removable tooth positioning appliances and would not distribute the Sprague tool in combination with the removable tooth positioning appliance to patients for home use.

9. In accordance with the foregoing, the aforementioned long felt need is satisfied by the present invention of a dental system for positioning teeth comprising: a removable tooth positioning appliance for aligning teeth of a patient; and an apparatus comprising a handle portion, a member extending from the handle portion and having a distal end, and an engagement block having a tapered edge for engaging an edge of the tooth positioning appliance, the engagement block protruding from the working portion at or near the distal end.

10. In accordance with the foregoing, the aforementioned long felt need is satisfied by the present invention of a method of removing a removable tooth positioning appliance from teeth of a patient comprising: providing an apparatus having a handle portion, a member extending from the handle portion and having a distal end, and an engagement block having a tapered edge, the engagement block protruding from the member at or near the distal end; positioning the tapered edge of the member near an edge of the tooth positioning appliance; inserting the tapered edge between the tooth positioning appliance and the teeth of the patient; and exerting force to the handle portion thereby causing the tooth positioning to release from the teeth of the patient.

11. I, Wm. Randol Womack, do hereby swear, affirm, and attest that all statements made in paragraphs 1-10 above are true and correct and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like are so made under the penalties of perjury, and that any false statements may jeopardize the validity of the present application or any patent issued thereon.

Date: 9-27-2005

Wm R Womack, D.D.S
Dr. Wm. Randol Womack, D.D.S.

To: Johathan Nicozisis

August 31, 2005

Re: CV for Dr. Wm. Randol Womack

Dental Education:

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| University of Missouri School of Dentistry | DDS degree | 1963 |
| Eastman Dental Center | Pedo Internship | 1964 |
| Eastman Dental Center | Orthodontic degree | 1966 |

Practice Experience:

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|----------------------|--------------|----------------|
| Clovis, New Mexico | Orthodontics | 1966 – 1972 |
| Phoenix, Arizona | Orthodontics | 1972 – 1997 |
| Retired | | 1997 – 1999 |
| Invisalign Certified | Orthodontics | 1999 – Present |

Current Practice:

| | | |
|-----------------|-----------------------|--------------------|
| Dr. Larry Davis | 5310 W Thunderbird Dr | Glendale, AZ 85306 |
| Employment | Orthodontics | Part time |

| | | |
|---------------------------|---------------------------------|----------------------|
| Wm. R. Womack.DDS, PC | 15050 N 69 th Street | Scottsdale, AZ 85253 |
| Invisalign Treatment Only | Private Practice | Part time |

Additional Employment:

Align Technology:

Independent Contractor agreement for Clinical Education Workshops

I have developed and presented Invisalign Provider Workshop Educational Programs since 2001, Nationally and Internationally.

This has included:

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|--------------------------------|---|
| Invisalign Orthodontic Summit | 2002,03,04 |
| Invisalign Provider Workshops: | |
| 2002 | 20 presentations (USA) |
| 2003 | 20 presentations (USA) |
| 2004 | 10 presentations (USA) 1 presentation - International (Milan, Italy) |
| 2005 | 10 presentations (USA) 3 presentations - International (London, Berlin, Rome - October 2005) |

Practice Experience with Invisalign:

1. Submitted over 500 Cases – Finished over 350 Cases
2. Member of Align Alpha Group
3. Member of Align Speakers Bureau
4. Member of Align Clinical Advisory Board
5. Associate Professor – Department of Orthodontics – University of the Pacific, School of Dentistry, San Francisco, CA
6. Published Articles:
 - a. American Dental Assistants Journal – 2002 Case Report
 - b. American Journal of Orthodontics/Facial Orthopedics - 2002 Case Report

Wm. Randol Womack, D.D.S.
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